

SENT VIA EMAIL

January 05, 2020

Dr. Peter Marks
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
W071-3128
Silver Spring, MD 20993-0002
Email: Peter.Marks@fda.hhs.gov

Re: *Lipid Nanoparticles in COVID-19 Vaccines*

Dear Dr. Marks:

We write on behalf of our client, Informed Consent Action Network (“ICAN”). As you are aware, the Pfizer and Moderna COVID-19 vaccines include mRNA in a lipid nanoparticle (“LNP”). A 2018 study titled [Lipid Nanoparticles: A Novel Approach for Brain Targeting](#) states, “...lipid nanoparticles are taken up readily by the brain because of their lipophilic nature. The bioacceptable and biodegradable nature of lipid nanoparticles makes them less toxic and suited for brain targeting.” The article also states, “these nanostructures need to be investigated intensively to successfully reach the clinical trials stage.”

There is also support for the proposition that the body is primed to have an immune reaction to the LNPs in these COVID-19 vaccines from the first dose such that the second dose is far more reactogenic. An article titled [Side Effects and COVID-19 Vaccines: What to Expect](#), published by Johns Hopkins states, “Side effects were more frequent after the second dose in the vaccine trials.”¹ This event is demonstrated in [Exogenous nanoparticles and endogenous crystalline molecules as danger signals for the NLRP3 inflammasomes](#), which provides support that increasingly inflammatory side-effects observed in the vaccine arm of the trial are attributable to LNPs and that they get worse with repeated injection. This increased reactogenicity is clearly illustrated in COVID-19 Clinical Trials for both the Pfizer² and Moderna.³

¹ <https://www.jhsph.edu/covid-19/articles/side-effects-and-covid-19-vaccines-what-to-expect.html>.

² <https://www.fda.gov/media/144245/download> at pp. 34-38.

³ <https://www.fda.gov/media/144452/download> at pp 59-62.

If LNPs from the vaccine, which contain the mRNA, are entering brain tissue and an immune reaction is occurring during the second dose to these LNPs, does this pose a safety concern to vaccine recipients?

ICAN remains dedicated to ensuring that the American public is capable of giving or obtaining informed consent with regard to any COVID-19 vaccines. To that end, ICAN asks that you consider the question posed herein and provide support for the substance of any response provided. We would welcome providing any additional information or meeting with you to discuss these requests.

Very truly yours,

/s/ Aaron Siri

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